

Notice of Allowability

Application No.

10/659,063

Examiner

Michael C. Henry

Applicant(s)

FINK ET AL.

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06/05/07.
2. ☒ The allowed claim(s) is/are 1-6.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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Examiner's Amendment/Reasons for Allowance

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Holliday C. Heine (Reg # 34,346) on 9/28/07. It should be noted that the support for the amendment of claim 1 is found on page 10 of applicant's specification.

The application has been amended as follows:

AMENDMENT TO THE CLAIMS

1. (Currently Amended) A method for treating an inflammatory condition, said method comprising the steps of:

providing a patient having an inflammatory condition; and
administering to said patient a therapeutically effective amount of a composition comprising a compound selected from the group consisting of cyclic adenosine diphosphate ribose (cADPR), or a functional analogue or derivative agonist thereof, cADPR having a stabilized phosphodiester linkage replacement, cADPR having a conformationally locked sugar ring and cADPR having a N3'→ P5' phosphoroamidate replacement, wherein said compound is in a form that is accessible to a receptor molecule, wherein said composition is conveyed in a pharmaceutically acceptable carrier vehicle, and wherein said composition reduces the degree of said inflammatory condition in said patient.

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2. (Original) The method of claim 1, wherein said inflammatory condition is selected from the group consisting of intestinal epithelial inflammation, endotoxemia, sepsis, hemorrhagic shock and pancreatitis.
3. (Original) The method of claim 2, wherein said intestinal epithelial inflammation is Crohn's disease or ulcerative colitis.
4. (Original) The method of claim 1, wherein said composition is administered to said patient enterally.
5. (Original) The method of claim 4, wherein said composition is administered using an enteric-coated formulation.
6. (Original) The method of claim 1, wherein said composition is administered to said patient systemically.
7. (Cancelled)
8. (Cancelled)
- 9-13 (Canceled).

The following is an examiner's statement of reasons for allowance: The examiner has found claims 1-6 to be unobvious over the prior art of record and therefore to be allowable over the prior art of record. The present invention relates to a method for treating of an inflammatory condition in a patient, by administering to said patient a therapeutically effective amount of a composition comprising cyclic adenosine diphosphate ribose (cADPR) and specific ADPR modified compounds." The prior art does not teach or suggest the use of cyclic adenosine diphosphate ribose (cADPR) nor the cADPR modified compounds to treat inflammation as claimed in the instant invention.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry



Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

September 28, 2007.